IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEXUS PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	C.A. No. _____
	)	
v.	)	
	)	**JURY TRIAL DEMANDED**
EXELA PHARMA SCIENCES, LLC,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff Nexus Pharmaceuticals, Inc. ("Nexus" or "Plaintiff") by its undersigned attorneys, for its Complaint against defendant Exela Pharma Sciences, LLC ("Exela" or "Defendant"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of Defendant's manufacturing, using, offering for sale, and selling an ephedrine sulfate 25 mg/5 mL (5 mg/mL) solution in a 5 mL prefilled syringe under the brand name AKOVAZ that infringes claims of Nexus's U.S. Patent No. 11,426,369 ("the '369 patent" or "the patent in suit").

PARTIES

2. Nexus is a corporation organized and existing under the laws of the State of Illinois, having its principal place of business at 400 Knightsbridge Parkway, Lincolnshire, Illinois.

3. Nexus is the holder of New Drug Application No. 213407 for EMERPHED®, (ephedrine sulfate) 50mg/10ml (5 mg/mL) IV solution. EMERPHED® was the first FDA-approved "ready to use" formulation with a 5 mg/mL concentration.

4. Nexus applied for and obtained patents related to its inventions for the ready to use 5 mg/mL concentration, including the '369 patent. Nexus is the owner and assignee of the '369 patent.

5. Exela is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1245 Blowing Rock Blvd, Lenoir, NC, 28645.

6. Upon information and belief, Exela is a pharmaceutical manufacturer and seller that specializes in "the development and manufacturing of generic and proprietary sterile injectable products with high barriers to market entry, via an Abbreviated New Drug Approval or 505(b)(2) regulatory pathway."[1]

7. Upon information and belief, Exela derives substantial revenue from the manufacture, compounding, and/or sale of generic pharmaceutical products throughout the United States, including in Delaware.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. Personal jurisdiction and venue are proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because Exela is incorporated in Delaware. Exela is a company organized and existing under the laws of the State of Delaware, is registered to do business in this State, and has appointed a registered agent to accept service.

[1] Corporate Overview, https://www.exelapharma.com/overview/ (last visited August 20, 2022).

10. On information and belief, Exela has manufactured and will manufacture a prefilled syringe product pursuant to its sNDA No. 208289/S-006 and has and will continue to offer for sale and sell its infringing prefilled syringe product in the United States, including in Delaware.

BACKGROUND

11. EMERPHED® is sold and marketed under New Drug Application No. 213407, which was approved by the FDA in April 2020.

12. Ephedrine, the active ingredient in EMERPHED®, is an alpha- and beta-adrenergic agonist and a norepinephrine-releasing agent. EMERPHED® is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

13. The '369 patent, entitled "Compositions comprising Ephedrine or an ephedrine salt and methods of making and using same" was duly and legally issued on August 30, 2022. Exhibit A.

14. The '369 patent claims are directed to a shelf-stable, ready to use ephedrine sulfate composition.

15. The'369 patent is valid and duly issued, and will not expire until at least May 16, 2040.

16. Upon information and belief, NDA No. 208289 for an ephedrine sulfate injection product to be marketed under the trade name AKOVAZ was originally approved by the FDA on or about April 29, 2016. Upon information and belief, the product described in NDA No. 208289 at the time of approval required dilution prior to administration and thus was not considered a ready to use ephedrine injection.

17. Upon information and belief, Exela acquired NDA No. 208289 on or about June 30, 2020.

18. Exela filed a supplemental New Drug Application sNDA No. 208289/S-006 on or about November 10, 2020, seeking FDA approval to market a shelf stable, ready to use prefilled syringe (PFS) composition of ephedrine sulfate with a 5 mg/mL concentration that requires no dilution prior to administration ("Exela's Akovaz PFS Product").

19. Exela is the present holder of sNDA No. 208289/S-006.

20. By letters dated February 1, 2022, May 1, 2022, and July 25, 2022 ("the Nexus Letters"), Nexus notified Exela regarding then-pending applications and the continuing nature of additional applications, inviting Exela to continue monitoring Nexus's patents for applicability to Exela's prefilled syringe product.

21. Exela responded to the February 1 Nexus letter, but did not respond to the May 1 or July 25 letters sent by Nexus. Nexus reached out again after the U.S. Patent and Trademark Office issued a Notice of Allowance, saying that a pending application would soon issue to become the '369 approved patent and invited the parties to discuss. Nexus and Exela did have discussions, but did not come to terms about any Nexus patent.

22. The Akovaz PFS Product is a shelf-stable, ready-to-use ephedrine sulfate composition that meets each and every limitation of the '369 patent, either literally or under the doctrine of equivalents.

23. Exela is continuing to market its product despite notice of infringement. Exela's infringing product threatens Nexus's existing and new customers, market share, price erosion, and distribution channels because of Exela's growing marketing.

24. Exela's acts of infringement of the '369 patent were and are willful, as Exela was on notice of Nexus's patent claims and the fact that the '369 patent would issue and took no action,

and such acts have caused and will continue to cause substantial damages and irreparable harm to Nexus.

COUNT I – INFRINGEMENT OF
U.S. PATENT NO. 11,426,369 UNDER 35 USC §271(a), (b), (c), and §154(d)

25. Nexus repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

26. Nexus is the assignee and owner of all right, title, and interest in the '369 patent and Nexus has the legal right to enforce the patent, sue for infringement, and seek equitable relief and damages.

27. The '369 patent is valid, enforceable, and was duly issued in compliance with Title 35 of the United States Code.

28. Upon information and belief, Exela has infringed and is continuing to infringe, the patented invention of at least claim 1 of the '369 patent by making, using, offering for sale, selling, and/or importing the Akovaz PFS Product, including by offering the Akovaz PFS Product for sale in the United States, in violation of 35 U.S.C. § 271(a), (b), and (c).

29. The foregoing actions and continued sales by Exela constitute and will constitute infringement of the '369 patent in violation of 35 U.S.C. § 271(a), (b), and (c).

30. Upon information and belief, Exela has acted with full knowledge of the '369 patent and without a reasonable basis for believing that it would not be liable for infringing the '369 patent.

31. Before the '369 patent issued, the Patent Office published the application and pending claims. Nexus provided to Exela actual notice of the ongoing applications, including the application that resulted in the '369 patent. Exela makes, uses, offers for sale, and sells products made by the claimed process as claimed in thep published patent application. Exela is liable for

pat least a reasonable royalty for the time period from the published patent application through patent issuance, under 35 U.S.C. §154(d).

32. For manufacturing, using, offering to sell, and selling beginning on the date of patent issuance, Exela is liable for full patent damages, including lost profits and/or a reasonable royalty.

33. Nexus informed Exela of the issuance of the '369 patent. Exela was placed on actual notice of the '369 patent and applications at least by the Nexus Letters, yet Exela persisted with its infringing activity, and is continuing to do so willfully.

34. This case is "exceptional," and Nexus is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

35. Unless Exela is enjoined from infringing the '369 patent, Nexus will suffer irreparable injury.

REQUEST FOR RELIEF

WHEREFORE, Nexus requests the following relief:

a. A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Exela's Akovaz PFS Product before the expiration of the '369 patent (including any regulatory extension), will infringe the '369 patent;

b. A judgment that the '369 patent is valid and enforceable;

c. An order for preliminary and permanent injunction;

d. An award, pursuant to 35 U.S.C. §§ 154(d) § 284, of damages or other monetary relief to compensate Nexus for Exela's engagement in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Exela's Akovaz PFS Product, or any product the

making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '369 patent;

e. Awarding Nexus enhanced damages;

f. A judgment pursuant to 35 U.S.C. § 285 that this case against Exela is an exceptional case and an award of attorneys' fees and costs; and

g. Such further and other relief as this Court may deem just and proper.

/s/ Kelly E. Farnan

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